Pharmacy Medical Necessity Guidelines: Drugs with Quantity Limitations

Effective: July 20, 2020

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	RX	Department to Review	RXUM

These pharmacy medical necessity guidelines apply to the following:

Commercial Products

☒ Tufts Health Plan Commercial products – large group plans
☒ Tufts Health Plan Commercial products – small group and individual plans
☒ Tufts Health Freedom Plan products – large group plans
☒ Tufts Health Freedom Plan products – small group plans
- CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Tufts Health Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product)
☐ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans
☐ Tufts Health RITogether – A Rhode Island Medicaid Plan

Fax Numbers:

RXUM: 617.673.0988

Note: This guideline does not apply to Medicare Members (includes dual eligible Members).

OVERVIEW

The plan limits the quantity of selected medications that a Member can receive, for clinical and/or cost reasons. A physician may submit a request for a medical exception to the Tufts Health Plan Pharmacy Utilization Management Department in cases where it is medically necessary to exceed these quantity limits.

COVERAGE GUIDELINES

The plan may authorize additional quantities for drugs that are restricted under the Quantity Limitations (QL) Program (with the exception of Cialis [tadalafil], Levitra [vardenafil], Staxyn [vardenafil], Stendra [avanfil], and Viagra [sildenafil]) for Members who meet the following criteria:

1. Physician documentation that the quantity of medication needed to clinically manage the patient's disease state within a given time frame is greater than the current quantity allowed under the QL program and that this amount is the minimum necessary therapeutic quantity.

Note: If using Viagra (sildenafil) for the treatment of pulmonary hypertension, please refer to Clinical Coverage Criteria entitled "Pulmonary Hypertension Medications".

Note: If using Cialis 5 mg (tadalafil) to treat the signs and symptoms of benign prostatic hyperplasia (BPH) please refer to Coverage Criteria entitled "Cialis (tadalafil) for BPH".

Note: The plan quantity limitation for the treatment of erectile dysfunction with Cialis (tadalafil), Levitra (vardenafil), Staxyn (vardenafil), Stendra (avanfil) and Viagra (sildenafil) is 4 tablets/30 days total of any combination of Cialis (tadalafil), Levitra (vardenafil), Staxyn (vardenafil), Stendra (avanfil) and Viagra (sildenafil). Not covered for Members 17 years of age or younger (No exceptions).

Amendment A

Hyperemesis Gravidarum Coverage Criteria

The plan will approve an override of the quantity limitation for a 5-HT3 Receptor Antagonist when the following criteria are met:

1. The patient has failed, or is unable to tolerate one of the following:
    a. Pyridoxine (Vitamin B6) in combination with doxylamine

OR

    b. Pyridoxine (Vitamin B6) in combination with metoclopramide

Amendment B

Opioid Coverage Criteria

The plan may authorize requests for over the quantity limitation for opioid analgesics when the following criteria are met:

1. The member is diagnosed with sickle cell-related, cancer-related, or end-of-life pain

OR

2. The Member has a diagnosis of pain:

AND

   a. The Member signed a pain agreement consistent with the American Academy of Pain Management guidelines

AND

   b. The analgesic is prescribed by or in consultation with a pain specialist, addiction specialist, palliative care specialist, hematologist/oncologist, physiatrist, rheumatologist or headache specialist (board certified) OR there is a plan for the member to be referred to a pain specialist, addiction specialist, palliative care specialist, hematologist/oncologist, physiatrist, rheumatologist or headache specialist (board certified) OR rationale provided why the member is not a candidate to see a specialist

AND

   c. The risks of use of a high dose schedule II, III, or IV analgesic use (e.g., tolerance, dependence, respiratory depression, cognitive impairment) have been discussed with the member

AND

   d. The provider has a plan to monitor for signs of misuse, abuse, and addiction during therapy

AND

   e. The provider has a taper plan in place or has a rationale as to why a dose taper is not appropriate at this time.

LIMITATIONS

1. Duration of coverage will be determined based on one of the following:
   - The specified duration of approval in existing coverage criteria for the requested drug or drug class
   - The length of treatment required for the requested drug and indication according to the medication's FDA-approved packet insert
2. Duration of approval for opioid analgesic medications over the quantity limit is one year.
3. Samples, free goods, or similar offerings of the requested medication do not quality for an established clinical response or exception but will be considered on an individual basis for prior authorization.

CODES

None

REFERENCES

1. Niebyl, Jennifer R. Nausea and Vomiting in Pregnancy. *New England Journal of Medicine*. 2010;363:1544-50.
2. Practice Bulletin No. 153: Nausea and vomiting of pregnancy. September 2015. American College of Obstet Gynecol 2015;126:e12-24.
3. The American Academy of Pain Management. Prescribing issue. Opioid agreement & contracts. URL: http://www.naddi.org/aws/NADDI/asset_manager/get_file/32898/opioidagreements.pdf Accessed 2016 March 28.

APPROVAL HISTORY

October 2001: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

- July 12, 2005: No changes.
- September 13, 2005: For Amendment A, change the topic from "Hyperemesis Coverage Criteria" to "Hyperemesis Gravidarum Coverage Criteria." Under criteria #1 for Amendment A, Hyperemesis Gravidarum Coverage Criteria, Delete from the list of drugs: Dimenhydrinate (Dramamine), Metoclopramide (Reglan), Promethazine (Phenergan) or Prochlorperazine (Compazine). Add: Meclizine (Antivert), Promethazine (Phenergan). Delete criteria #2 for Amendment A, "The patient has required one course of treatment for hydration including intravenous fluids."
- August 8, 2006: Added generic descriptions to Cialis, Levitra, and Viagra: tadalafil, vardenafil, and sildenafil respectively
- July 10, 2007: No changes.
- July 8, 2008: No changes.
- November 11, 2008: Added "minimum necessary therapeutic quantity" to pharmacy coverage guidelines for drug authorization requests seeking to exceed a dispensing limit. Modified dispensing limitation language for Cialis (tadalafil), Levitra (vardenafil), and Viagra (sildenafil) to clarify that the dispensing limitation applies to all medical conditions (with the exception of Viagra (sildenafil) for the treatment of pulmonary hypertension).
- November 10, 2009: No changes.
- January 1, 2010: Removal of Tufts Medicare Preferred language (separate criteria have been created specifically for Tufts Medicare Preferred).
- November 9, 2010: Modified all "Dispensing limitation (DL)" language to "Quantity limitation (QL). Replaced the products pyridoxine (Vitamin B6), meclizine (Antivert®), promethazine (Phenergan®) for hyperemesis gravidarum coverage with pyridoxine (Vitamin B6) in combination with dimenhydramine and metoclopramide. Added "maximum six week course" to the 5-HT3 Receptor Antagonist criteria.
- November 15, 2011: Added the note to refer to Cialis (tadalafil) for BPH Pharmacy Medical Necessity Guidelines if using Cialis for the indication of BPH
- May 8, 2012: Effective August 1, 2012, added Amendment B "Smoking Cessation Annual Dispensing Limit".
- August 14, 2012: Removed dimenhydramine requirement from coverage criteria for hyperemesis gravidarum, product has been discontinued. Clarified that for smoking cessation drugs, quantity limitations will be reviewed within the annual limits
- September 11, 2012: Added Staxyn (vardenafil) and Stendra (avanfil) to exception for authorization of additional quantities
- July 9, 2013: No changes.
- July 8, 2014: Removed the limitation allowing only a six-week course of treatment for 5-HT3 receptor antagonists for the treatment of hyperemesis gravidarum. Removed Amendment B: Smoking Cessation Annual Duration Limit (for Massachusetts only) Tufts Health Plan will not authorize requests over the annual limit for smoking cessation products. Zyban (bupropion), Buproban, Nicotrol Inhaler, and Nicotrol Nasal Spray – Annual limit of 90 days per calendar year. Chantix – Annual limit of 24 weeks per calendar year. Tufts Health Plan will review requests for coverage over the quantity limitations for smoking cessation products within the annual limits based on the Pharmacy Coverage Guidelines for Drugs with Quantity Limitations above.
- September 16, 2015: No changes.
- January 1, 2016: Administrative change to rebranded template applicable to Tufts Health Direct.
- August 9, 2016: No changes.
- November 15, 2016: Administrative update to remove all gender language from Medical Necessity Guideline. "Not covered for men 17 years of age or younger, or for women" was changed to "Not covered for Members 17 years of age or younger" in the Note describing coverage of oral erectile dysfunction medications.
- February 14, 2017: Added the following clarifying limitation regarding approval duration "Duration of coverage will be determined based on the length of treatment required for the requested drug and indication according to the medication's FDA-approved package insert."
- April 11, 2017: Administrative update, Adding Tufts Health RITogether to the template.
- October 17, 2017: Added a treatment option of Pyridoxine (Vitamin B6) in combination with doxylamine to the prerequisite list on hyperemesis criteria (amendment A) for 5-HT3 receptor antagonists' coverage authorization.
- October 16, 2018: No changes
- November 13, 2018: Effective January 8, 2019, updated the Limitation regarding duration of approval for Drugs With Quantity Limitations.

- January 18, 2019: Effective April 1, 2019, added criteria for opioid analgesic medications and updated duration of approval to opioid analgesic medications to one year. Administrative changes made to template.
- October 15, 2019: Effective January 1, 2020, updated the opioid coverage criteria to include sickle cell-related pain and remove malignant pain as an approvable diagnosis. Also added palliative care specialist, rheumatologist, and headache specialists (board certified) to the list of approvable specialists.
- July 14, 2020: Added the following limitation: Samples, free goods, or similar offerings of the requested medication do not quality for an established clinical response or exception but will be considered on an individual basis for prior authorization.

BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member’s benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.